



Health Technology Review	
Technology Ref.:	HTA-23022
Technology Name:	Second Generation Fecal Immunochemical test (FIT).
Approvals by International Bodies:	FDA Technology is CE marked
Company name:	Pinnacle BioLabs
Agent in UAE:	Pharma Plus Drug Store LLC
Email:	zine@pharmagroup.ae

Short Description of the Technology:	<p>The Second Generation FIT™ Fecal Immunochemical Test employs a unique combination of polyclonal and monoclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. In less than five minutes, elevated levels of human hemoglobin as low as 50ng Hb/mL can be detected and positive results for higher levels of hemoglobin can be seen in the test as early as 2-3 minutes.</p> <p>Intended Use: For the determination of human hemoglobin in feces by professional laboratories or physician's offices. Useful as an aid in the detection of lower GI bleeding, colorectal cancer, et.</p>
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>the second-generation Fecal immunochemical test (FIT) is a screening test for colon cancer. It tests for hidden blood in the stool, which can be an early sign of cancer. FIT only detects human blood from the lower intestines. Medicines and food do not interfere with the test. So, it tends to be more accurate and has fewer false positive results than other tests.</p> <p>In the UAE, colon cancer is the most common cancer among males and the third most common cancer in females. Routine screening is recommended for everyone over the age of 40 to prevent colon cancer. And I believe the FIT test figure could be reduced as the disease is preventable and treatable if caught early.</p>	
Advantages	Disadvantages
supposedly simple to perform and no need for analytical instrumentation.	color develops dynamically and true negatives become positive with a prolonged read time and results may be falsely negative if read too early.
can be done by others in health care than professionals in laboratory medicine, and easy to store since no refrigeration of components needed.	
no diet restrictions, no medicine restrictions	
inexpensive	

results are available for clinical decision-making within minutes.

FDA Approval.

We recommend **approval this technology** with the following conditions:

The approval on using Second Generation Fecal Immunochemical test (FIT).

1. performed by medical professional.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image





Population, setting and intended user for Technology “Second Generation Fecal Immunochemical test (FIT).”

- **Population/ Intended User.**
 - aged between 40-65 years.
 - Patient with hemoglobin in feces.
- **To be performed by:**
 - By medical professional .
- **Clinical Setting:**
 - Hospitals, special Laboratory centers
- **Condition of use:**
 - A personal history of colorectal cancer or certain types of polyps
 - A family history of colorectal cancer
 - A personal history of inflammatory bowel disease (ulcerative colitis or Crohn’s disease)
 - A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch.
 - syndrome (hereditary non-polyposis colon cancer or HNPCC).
 - A personal history of getting radiation to the abdomen (belly) or pelvic area to treat a prior cancer.
- **Exclusion criteria:**
 - Menstrual bleeding.
 - Bleeding hemorrhoids.
 - Constipation bleeding.
 - Urinary bleeding.

Alcohol and certain medications such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroid and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients.